



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-22-1260]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled "Maritime Illness Database and Reporting System (MIDRS)" to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on October 25, 2021 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

- (c) Enhance the quality, utility, and clarity of the information to be collected;
- (d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and
- (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Maritime Illness Database and Reporting System (MIDRS) (OMB Control No. 0920-1260, Exp. 04/30/2022) - Revision - National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Under Foreign Quarantine Regulations (45 CFR 71), §71.21(c) for "report of illness" and §71.41 "general provisions" for sanitary inspections, the Vessel Sanitation Program (VSP) in the National Center for Environmental Health (NCEH) takes the CDC lead on overseeing acute gastroenteritis (AGE) illness surveillance, AGE outbreak investigations, and sanitary inspections. The VSP's jurisdiction includes passenger vessels carrying 13 or more people sailing from foreign ports and within 15 days of arriving at a U.S. port. Data collected allows VSP to quickly detect AGE outbreaks, provide epidemiologic and sanitation guidance to stop the outbreak, craft public health recommendations to prevent future outbreaks, and monitor AGE illness trends to identify important changes over time.

To continue this AGE surveillance, NCEH is requesting a revision of a three-year Paperwork Reduction Act (PRA) clearance for the Maritime Illness Database and Reporting System (MIDRS) (OMB Control No. 0920-1260; expiration date 04/30/2022). This information collection request (ICR) is revised to refine and update respondent types, frequencies of responses, information collection forms, recordkeeping requirements, and time burden

requested for AGE surveillance. CDC is also updating this ICR to include recordkeeping requirements related to VSP sanitation inspections.

The MIDRS data collection system consists of an electronic surveillance system that receives information through a web-based reporting portal 24 hours and four hours prior to arrival at a U.S. port. This data can also be submitted by phone, email, or fax and entered into MIDRS by VSP. AGE cases reported to MIDRS are totals for the entire voyage and do not represent the number of active AGE cases at any given port of call or at disembarkation.

In the past three years, the VSP has received 13,352 AGE reports to MIDRS. Since the first quarter of 2020, the COVID-19 pandemic disrupted the number of cruise ship voyages operating to U.S. ports of call. Between March 2020 and October 2021, cruise industry operations were suspended under a federally issued No Sail Order, and then subsequently under a Conditional Sailing Order to prevent the risk of introducing, transmitting, and spreading COVID-19 by cruise ship travelers. As a result, the number of AGE reports submitted to MIDRS in 2020 and 2021 were substantially lower (n=2,667 and n=1,717, respectively), compared to 2019 (n=8,968).

Thus, VSP revises its annual estimates to 9,000 MIDRS reports from approximately 300 ships arriving at U.S. ports 30 times per year. This number of arrivals reflects the number of times each cruise ship must submit a report to MIDRS in a given

year ($n=300 \times 30=9,000$). All arriving ships send 24-hour MIDRS reports (44% electronically [$n=132$]; 56% by phone, email, or fax [$n=168$]) to the VSP. A subset of approximately 80% of these ships may need to send four-hour MIDRS reports either electronically ($n=106$) or by phone, email, or fax ($n=201$) if the number of cases changes after submission of the initial report.

When AGE cases exceed the 2% alert threshold and the 3% outbreak threshold, special reports are sent to VSP. VSP estimates that 2% of ships reporting to MIDRS ($n=180$) per year are required to send up to four special report updates until they are four hours from port. VSP also requires these ships to begin sending at least one and up to 12 daily reports in the form of AGE logs to monitor and assess whether a cruise ship outbreak investigation (CSOI) may be warranted. If so, VSP conducts CSOIs under OMB Control Number 0020-1255 (expiration date 03/30/2022).

The daily report in the form of AGE logs and the 72-hour food/activity history template are used to document AGE cases among crew ($n=575$ per year) and passengers ($n=2,795$ per year). The ship's crew undergo additional worker assessments. For example, all crew members undergo a three-day pre-embarkation AGE illness assessment ($n=197,640$ per year based on an average of 1,080 crew per ship in 2019). Assuming five contacts and cabin mates per crew AGE cases, approximately 2,875 crew per year undergo additional screening and assessments such as initial, 24-hour, and 48-hour verbal interviews to assess AGE

status. Crew AGE cases must also undergo a last symptom check to obtain a return-to-work clearance. Documentation of these assessments and reports are maintained on the ship for at least 12 months (8,760 hours per year).

There are three types of respondents involved in AGE surveillance: cruise ship medical staff or other designated personnel who treat and report AGE cases to VSP, and the cruise ship crew and the cruise ship passengers who may become AGE cases. Of note, VSP does not request any identifiable information from or about the AGE cases; this information is collected and owned by the cruise line and maintained on the ship as part of the AGE case's medical record.

A fourth type of respondent is the cruise ship engineering staff who perform shipboard engineering and sanitation system maintenance. Such records must be maintained for at least 12 months (8,760 hours). VSP reviews these records during operational inspections to confirm they are available if needed, and if there is an AGE outbreak or report of unusual AGE illness for a particular voyage.

After careful consideration of the VSP and cruise industry experience in 2019 and the standard practices outlined in the VSP Operations Manual, CDC has revised its burden estimates for an increase of 6,312,230 annual responses (n=6,325,980) compared to that approved in 2019 (n=13,750). CDC also estimates the total annualized time burden is 5,592,688 hours, which is an increase of 5,591,150 hours compared to the previously approved

1,538 hours. This increase in annual time burden is based largely on more accurate estimation of the number of respondents, the number of responses, and adding the 12-month recordkeeping burden for both AGE surveillance records and for maintenance and sanitation records; this recordkeeping burden was not accurately accounted for in the prior ICR. There are no other costs to the respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
Cruise ship medical staff or other designated personnel	AGE Illness Report 24 hours before arrival (web)	132	30	3/60
	AGE Illness Report 24 hours before arrival (phone/email/fax)	168	30	3/60
	AGE Illness Report 4 hours before arrival (web)	106	30	3/60
	AGE Illness Report 4 hours before arrival (phone/email/fax)	134	30	3/60
	Special Reports exceeding 2%-3% AGE Threshold (web/phone/email/fax)	180	4	3/60
	Daily Reports of AGE Logs	180	12	3/60
	Recordkeeping of AGE Surveillance Records	300	1	8,760

Cruise ship crew	72-hour Food/Activity History Template (AGE cases)	575	30	10/60
	Three-day Pre-embarkation AGE Illness Assessment (all crew members)	197,640	30	3/60
	Interviews to Determine AGE Status (initial, 24-hr, 48-hr) (asymptomatic cabin mates and immediate contacts of symptomatic crew)	2,875	90	5/60
	Last Symptom Check and Return to Work Clearance (food and nonfood employees)	575	30	3/60
Cruise ship passengers	72-hour Food/Activity History Template (AGE cases)	2,795	30	10/60
Cruise ship engineering staff or other designated personnel	Recordkeeping of Engineering and Sanitation Records	300	1	8,760

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